ABSTRACT

An improved process for the preparation of levofloxacin hemihydrate

The present invention relates to an improved process for preparation of Levofloxacin hemihydrate having single individual impurity not more than 0.1 % and free from particulate matter & from the other enantiomer (R-form) which comprises dissolving levofloxacin technical grade in aqueous alkaline solution, treating the resulting solution with activated carbon at room temperature, removing the undissolved particulate matter filtration, bringing the pH of the aqueous alkaline levofloxacin solution to neutral using dilute mineral acid, removing the precipitated particulate matter by filtration,acidifying the resulting solution, treating the acidified solution with activated carbon at room temperature,filtering the undissolved particulate matter by filtration, neutralizing the acidic solution, filtering again to remove any particulate matter present and, extracting the resulting product with chlorinated solvent and concentrating under vacuum using aqueous tetrahydrofuran or in admixture with other organic solvents to get highly pure levofloxacin hemihydrate having single individual impurity is less than 0.1% and free from particulate matter & from the other enantiomer (R-form).